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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,225	08/02/2001	Glen A. Evans	P-EA 4672	8914

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT PAPER NUMBER

1652

DATE MAILED: 06/09/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/922,225

Applicant(s)

EVANS, GLEN A.

Examiner

Elizabeth Slobodyansky

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1652

DETAILED ACTION

Claims 1-35 are pending.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 31 and 32, drawn to a polypeptide of SEQ ID NO:2 and a method of use thereof, classified in class 435, subclass 15.
- II. Claims 3-6, drawn to a DNA encoding SEQ ID NO:2, classified in class 536, subclass 23.2.
- III. Claim 7, drawn to a mannosyl transferase of SEQ ID NO:4, classified in class 435, subclass 193.
- IV. Claims 8 and 9, drawn to a DNA comprising SEQ ID NO:3, classified in class 536, subclass 23.5.
- V. Claims 10 and 11, drawn to a DNA comprising SEQ ID NOs: 16-117, classified in class 536, subclass 23.5.
- VI. Claims 12 (in part), 13, 18 (in part) and 19, drawn to methods of diagnosing or predicting a bipolar disorder using as a probe SEQ ID NO:1, classified in class 435, subclass 6.

Art Unit: 1652

- VII. Claims 12 (in part), 14, 18 (in part) and 20, drawn to methods of diagnosing or predicting a bipolar disorder using as a probe SEQ ID NO:3, classified in class 435, subclass 6.
- VIII. Claims 12 (in part), 15, 18 (in part) and 21, drawn to methods of diagnosing or predicting a bipolar disorder using as a probe SEQ ID NO:5, classified in class 435, subclass 6.
- IX. Claims 12 (in part), 16 and 17, drawn to a method of diagnosing or predicting a bipolar disorder using as an antibody against a polypeptide encoded by SEQ ID NO:3, classified in class 435, subclass 7.1.
- X. Claims 18 (in part) and 22-24, drawn to a method of diagnosing or predicting a bipolar disorder using as an agent that binds to a mannosyl transferase of SEQ ID NO:2, classified in class 435, subclass 7.71.
- XI. Claims 18 (in part) and 25-30, drawn to a method of diagnosing or predicting a bipolar disorder by measuring activity of a mannosyl transferase, classified in class 435, subclass 7.91.
- XII. Claims 33-35, drawn to a non-human transgenic animal, classified in class 800, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Art Unit: 1652

Inventions I, III and inventions II, IV, V are patentably distinct because a polypeptide and a DNA are different compounds each with its own chemical structure and function, and they have different utilities. The DNA molecules of inventions II, IV, V are not limited in use for the production of polypeptides, including polypeptides of inventions I, III and can be used as probes in methods of inventions VI-VIII, and polypeptides of inventions I and III can be obtained by a materially different method such as by the biochemical purification or chemical synthesis.

Each of inventions I, III, each of inventions II, IV, V and each of inventions VI, VII, VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polypeptides and the polynucleotides encoding them and methods of use thereof. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

Inventions II and VI, IV and VII, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant

Art Unit: 1652

case a DNA of SEQ ID NO:1 or SEQ ID NO:3 can be used for the production of an encoded polypeptide.

Methods of inventions VI-XI are patentably distinct as drawn to materially different methods employing different products such as DNA, antibody and a binding agent and having different effects and utilities.

Inventions I-V and invention XII are patentably distinct because a polypeptide and a DNA are single chemical compounds while a transgenic organism is a live organism comprising a vast number of compounds acting in accord.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper.

Invention V, claims 10 and 11, is directed to the patentably distinct species of a SNP comprising a sequence of any one of SEQ ID NOs: 16-117.

If invention V is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 10 and 11.

Art Unit: 1652

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Ms. Astrid Spain on June 6, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Art Unit: 1652

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.



Elizabeth Slobodyansky, PhD
Primary Examiner

June 6, 2003